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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/785,997	01/22/97	REICHARD	P 235299/96001

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EXAMINER	
DELACROIX MUIRHEI,C	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 12/10/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Below is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

DATE MAILED:

ADVISORY ACTION

■ *THE PERIOD FOR RESPONSE*

a) ☐ *is extended to run* _____ *or continues to run* 5 months *from the date of the final rejection.*

b) ☐ *expires three months from the date of the final rejection or as to the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for response expire later than six months from the date of the final rejection.*

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response as set forth in b) above.

☐ *Appellant's Brief is due in accordance with 37 CFR 1.192(a).*

■ *Applicant's response to the final rejection, filed* June 22, 1998 *, has been considered with the following effect, but is not deemed to place the case in condition for allowance.*

1. ☐ *The proposed amendments to the claim/and or specification will not be entered and the final rejection stands because:*

   a. ☐ *There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.*

   b. ☐ *They raise new issues that would require further consideration and/or search. (See note).*

   c. ☐ *They raise the issue of new matter (See note).*

   d. ☐ *They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.*

   e. ☐ *They present additional claims without cancelling a corresponding number of finally rejected claims.*

   NOTE: ___

2. ☐ *Newly proposed or amended claims* ___ *would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.*

3. ■ *Upon the filing of an appeal, the proposed amendment* ■ *will be entered* ☐ *will not be entered and the status of the claims will be as follows:*

Claims allowed: None
Claims objected to: None
Claims rejected: 15, 16, 18-24, 26-33

However;

■ Applicant's response has overcome the following rejection(s): the previous rejection under 35 USC 112, second paragraph, set forth in paragraph 2 the office action mailed June 22, 1998 and the previous rejection under 35 USC 112, paragraph 1, set forth in paragraph 3 of the office action mailed June 22, 1998.

4. ■ The affidavit, exhibit or request for reconsideration has been considered, but does not overcome the previous rejection under 35 USC 103(a), maintained in the office action mailed June 22, 1998, and the rejection under 35 USC 102(b) set forth in paragraphs 4-5 of the office action mailed June 22, 1998 for reasons given hereinbelow:

Applicant's declaration received April 1, 1998 was not found sufficient to overcome the reference to Felberbaum for reasons given previously in the office action mailed June 22, 1998. The declaration received Nov. 23, 1998 additionally fails to overcome the Felberbaum reference. First of all the declaration is insufficient in that it is not clear how said declaration serves to establish "same inventive entity" between the inventors in the instant application and the remaining author, Diedrich, K, in the prior art. Moreover, if the declaration is establishing "same inventive entity", then paragraphs 3 and 4 of the declaration appear to contradict each other. In paragraph 3, Applicant states that they are the original inventors of the disclosure in the Felberbaum reference, yet at paragraph 4 it is stated that the co-inventors Bouchard, Frydman, Devroey and Engel are not listed as co-authors on the Felberbaum reference because "they were not directly involved in carrying out this particular study". It is not clear to the Examiner to what "this particular study" refers. If it refers to the study in the article, then the coauthors are actually **not** the inventors of the subject matter disclosed in the reference and the reference remains a publication by "another". It is for these reasons that the rejection under 35 USC 103(a) over Diedrich in view of Felberbaum stands.

With respect to primary reference to Diedrich et al., Applicant argues that Diedrich does not disclose a method of treating infertility disorders wherein an improved dosage regime is employed, namely, lower dosages of .1 to .5 mg or single or dual dosages of 2 mg to 6 mg/day are administered to a patient in need thereof. Moreover, Applicant argues that the claimed method allows for suppression of LH without affecting FSH secretion, whereas Diedrich et al. discloses a method that suppresses LH surges but Diedrich teaches that patients are administered FSH at the beginning of treatment.

However, as stated in the office action mailed June 22, 1998, it is the Examiner's position that Applicant's arguments with respect to the administration of Cetrorelix in dosages of .1 to .5 mg or single or dual dosages of 2 mg to 6 mg/day, are not commensurate in scope with claims 15 and 21. Moreover, the Examiner maintains that Diedrich does disclose suppression of LH surges while also suggesting that under Cetrorelix treatment, suppression of FSH is less pronounced. Please see page 790, second full paragraph. It is for these reasons that the claims remain rejected.

Finally, concerning the rejection of claims 21, 22, 33 under 35 USC 102(b) over Diedrich, Applicant contends that Diedrich does not disclose a method of administering Cetrorelix starting at cycle day 1-10, 4-8 or 6-10 wherein ovulation can be induced between day 9-20 of the menstruation cycle; however, the Examiner disagrees. Diedrich et al. disclose a method of inducing ovarian stimulation in tubal sterile patients by administering a combination of exogenous gonadotrophins (HCG) and the LHRH antagonist Cetrorelix to said patients. Cetrorelix was administered at a dosage 3 mg daily **starting on day 7 of the menstrual cycle**. Please see the abstract; page 789, **Results**, first full paragraph; page 790, second column, first full paragraph; page 791, first column, third paragraph.

Claims 22 and 33 are anticipated by Diedrich because Diedrich discloses administration of the same active agent, i.e. Cetrorelix, to a patient using Applicant's claimed method steps. Accordingly, induction of ovulation between day 9 and 20 of the menstruation cycle is inherent.

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

Cecilia Tsang

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